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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR ·	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,530	06/15/2001	Derrick A. Richardson	485772003600	9930
7	590 06/17/2003	,		
Rimas Lukas			EXAMINER	
P.O. Box 3295 Half Moon Bay			LEWIS, PA	TRICK T
			ART UNIT	PAPER NUMBER
			1623	1
	• :		. DATE MAILED: 06/17/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

1.0							
		Application No. Applicant(s)		)			
Office Action Summary		09/882,530	RICHARDSO	RICHARDSON ET AL.			
		Examiner	Art Unit				
		Patrick T. Lewis	1623				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).  Status							
1) Responsive to communicat	tion(s) filed on <u>07 A</u>	oril 2003	:				
2a) ☐ This action is <b>FINAL</b> .	2b)⊠ This	s action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 1-25 is/are pending in the application.							
4a) Of the above claim(s) <u>24 and 25</u> is/are withdrawn from consideration.							
	5) Claim(s) is/are allowed.						
	6)⊠ Claim(s) <u>1-23</u> is/are rejected.						
7) Claim(s) is/are objec							
8) Claim(s) are subject to restriction and/or election requirement.  Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made o		priority under 35 U.	S.C. § 119(a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.						
<del>-</del>	2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) ☐ Acknowledgment is made of	a claim for domestic	priority under 35 U	S.C. § 119(e) (to a provi	sional application).			
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)			•				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6) Other:							
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### **DETAILED ACTION**

### **Election/Restrictions**

- 1. Applicant's election without traverse of Invention I (claims 1-23) in Paper No. 8 dated October 21, 2002 is acknowledged.
- 2. Claims 24-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8 dated October 21, 2002.

## Objections/Rejections Set For the in Office Action dated January 31, 2003

- 3. Claims 6-11, 14, 17, 21, and 23 were objected to because of the following informalities: depend from rejected claim.
- 4. Claims 9 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "at least one vent comprises four vents" renders the claim indefinite, as it is unclear as to the number of vents on the filter column.

5. Claims 1-5, 12-13, 15-16, 18-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Polak U.S. Patent 3,917,458 (Polak) and Padhye et al. U.S. Patent 5,808,041 (Padhye).

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Claims 1-5, 12-13, 15-16, 18-20, and 22 are drawn to a filter column comprising: a body having a passageway extending therethrough, said body comprising at least a first body portion, a second body portion, and a third body portion, where an outer diameter of said first body portion is greater that an outer diameter of said second body portion, and where said outer diameter of said second body portion is greater than an outer diameter of said third body portion; a filter located within said passageway, said filter adapted to isolate nucleic acids from said liquid sample; and a plurality of bearing surfaces on an outer surface of said body, at least one of said bearing surfaces being adapted to seat on at least one of the collection tubes, said plurality of bearing surfaces including at least a first bearing surface located between said first and second body portions, and a second bearing surface located between said second and third body portions.

Polak teaches a gas filtration system employing a column as shown in Fig. 1. The system comprises a column possessing at least three body portions wherein the body of the first portion (J) is greater than the diameter of the second portion (H) and the body of the second portion (H) is greater than the diameter of the third portion. The system also has a plurality of bearing surfaces.

Polak differs from the instantly claimed invention in that Polak does not teach the instantly claimed column dimensions nor does Polak teach the filter as being adapted for isolating nucleic acids. However, these deficiencies would have been obvious to one of ordinary skill in the art in light of the teachings of Padhye.

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Padhye teaches a mixture of silica gel and glass particles in combination with an aqueous solution of chaotropic salts to isolate DNA or RNA (column 3, lines 19-26). Padhye further teaches that if the silica materials are in a chromatography column, a suitable volume of a solution can be passed through the material in the column to substantially completely remove the chaotroic salts and other contaminants of concern [teaches use of filter material with columns].

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Polak and Padhye to obtain the instantly claimed invention. The column dimensions are seen to one of experimental design choice and as such are within the purview of the skilled artisan. It would have also been obvious to use the filter media taught by Padhye since Padhye teaches its suitability for isolating nucleic acids.

# Applicant's Response dated April 7, 2003

- 6. In the Response filed April 7, 2003, claim 9 was amended. Applicant presented arguments directed to the rejection of claims 1-5, 12-13, 15-16, 18-20, and 22 under 35 U.S.C. 103(a). Claims 1-25 are pending. Claims 24-25 are drawn to a nonelected invention. An action on the merits of claims 1-23 is contained herein below.
- 7. Applicant's arguments filed April 7, 2003 have been fully considered and have rendered the objection to claims 6-11, 14, 17, 21, and 23 moot.
- 8. Applicant's arguments filed April 7, 2003 have been fully considered and have overcome the rejection of claim 9 under 35 U.S.C. 112, second paragraph.

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9. Applicant's arguments with respect to claims 1-5, 12-13, 15-16, 18-20, and 22 under 35 U.S.C. 103(a) have been considered but are moot in view of the new ground(s) of rejection.

### Claim Rejections - 35 USC § 103

- 10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.

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- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 13. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over BIO-RAD, Life Science Research Products Catalog (1993), pages 57 and 60-63 (BIO-RAD).

Claims 1-23 are drawn to a filter column comprising: a body having a passageway extending therethrough, said body comprising at least a first body portion, a second body portion, and a third body portion, where an outer diameter of said first body portion is greater that an outer diameter of said second body portion, and where said outer diameter of said second body portion is greater than an outer diameter of said third body portion; a filter located within said passageway, said filter adapted to isolate nucleic acids from said liquid sample; and a plurality of bearing surfaces on an outer surface of said body, at least one of said bearing surfaces being adapted to seat on at least one of the collection tubes, said plurality of bearing surfaces including at least a first bearing surface located between said first and second body portions, and a second bearing surface located between said second and third body portions.

BIO-RAD describes a low-pressure chromatography column comprising a body having a passageway extending therethrough (page 62). The body of the column comprises three sections wherein the top section has a greater diameter than the middle section which has a greater diameter than the bottom section. The top section contains an end cap and a 10 mL reservoir. The middle section has a 2 mL be volume and contains a porous polymer bed support. The column described by BIO-RAD contains bearing surfaces adaptable to seat of collection tubes of different sizes.

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The instantly disclosed filter column differs from the column described by BIO-RAD in that: 1) BIO-RAD teaches the filter location within the second body as opposed to the third body as instantly claimed; 2) BIO-RAD does not describe the end cap having an annular lip; 3) BIO-RAD does not teach a column comprising vents; 4) BIO-RAD does not teach a column comprising protrusions; 4) BIO-RAD does not describe a column containing the instantly claimed dimensions; and 5) BIO-RAD does not teach a column comprising a fourth section.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify to teaching of BIO-RAD to obtain the instantly claimed filter column. The differences between BIO-RAD and the instantly claimed filter column are seen as one of design choice. In the absence of persuasive evidence that the particular configuration of the claimed column is significant, the instantly claimed filter column is indeed prima facie obvious.

#### Conclusion

Claims 1-25 are pending. Claims 24-25 are drawn to a nonelected invention. 14. Claims 1-23 are rejected. No claims are allowed.

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### Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD Examiner Art Unit 1623

ptl June 16, 2003 James O. Wilson

Supervisory Patent Examiner Technology Center 1600